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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,445	06/29/2004	Brian Scott Anderson	X-15430	2313
25885	7590	04/11/2006	EXAMINER	
ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			FIDEI, DAVID	
			ART UNIT	PAPER NUMBER
			3728	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/500,445	Applicant(s) ANDERSON, BRIAN SCOTT	
	Examiner David T. Fidei	Art Unit 3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/29/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

CLAIM CONSTRUCTION

1. In analyzing applicant's invention as set out in the pending claims, the examiner sets forth the following to aid in understanding the application of the prior art herein. Claims are to be given their broadest reasonable during prosecution, see *In re Priest*, 582 F.2d 33, 37 USPQ 11, 15 (CCPA 1978), and limitations from the specification will not be read into the claims, see, e.g. *In re Prater*, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997), see MPEP 2106.

In order to further limit the claim there must be some distinction based upon the intended use recited. "However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art, see M.P.E.P. § 2111.02 THE INTENDED USE MAY FURTHER LIMIT THE CLAIM IF IT DOES MORE THAN MERELY STATE PURPOSE OR INTENDED USE. The examiner can see no structural differences between the claimed invention and the prior art based upon the intended use recited of a case "for storing a portable medication delivery device". Also, the means recited claim 1 is being treated as a means plus function clause as provided by 35 USC 112 6th paragraph.

Claim Rejections - 35 USC § 112

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Since the medication delivery device is not a positive part of the claim it is not clear what the scope of claim 6 is. This claim is also confusing since "said storing means" has no antecedent basis and appears to "un-invoke" 35 USC 112 6th paragraph if the means for storing is now limited to specific structure rather than that structure along with equivalents thereof.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Riemenschneider et al (Patent no. 6,571,942). A case for medication delivery is disclosed comprising a first part 11 and a second part 12, each having an interior and exterior surface. Means 20 is located on the interior surface on at least on interior surfaces for storing medication as shown in figure 3. A desiccant 24 is held by the first part 11.

As to claims 2 and 7, the desiccant is held between the interior and exterior surfaces of the first part by and insert 20 forming a storage space as shown in figure 3.

4. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Flores et al (Patent no. 3,567,085). A case for medication delivery is disclosed comprising a first part 28 and a second part 10,16, each having an interior and exterior surface. Means, formed by the interior walls of 10, 16, are located on the interior surface on at least on interior surfaces for storing medication as shown in figure 2. A desiccant 42 is held by the first part 28.

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As to claims 2, this desiccant 42 within storage space 40 between the interior surface of the first part and the exterior surface of the first part.

As to claims 3 and 4, the interior surface defines a plurality of opening 54.

The hollow opening of vial 11 forms a recess of an interior surface for storing the medication delivery device "A" as recited in claim 6.

As to claim 7, the first part 28 comprises a shell shown by 30 and an insert 58 attached thereto. The storage space is formed between the shell 20 and insert 58 as shown in figure 2.

As to claim 8, the insert defines at least one opening 54.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lily (Patent no. 1,625,035) in view of Official Notice. The difference between the claimed subject matter and Lily resides in the kit including a desiccant held by the first part and in airflow communication with internal volume for limiting moisture buildup.

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The prior art shows that the use of a desiccant is notoriously well known in the container art, medical art and packaging field to protect the contents of a container. It would have been obvious to one skilled in the art at the time the invention was made to

REPLY BY APPLICANT OR PATENT OWNER TO THIS OFFICE ACTION

8. “In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to every ground of objection and rejection in this Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. The applicant’s or patent owner’s reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section. The reply must be reduced to writing (emphasis added)”, see 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

Pointing out specific distinctions means clearly indicating in the written response what features/elements or distinctions have been added to the claim/claims, where support is found in the specification for such recitations and how these features are not shown, taught, obvious or inherent in the prior art.

If no amendments are made to claims as applicant or patent owner believes the claims are patentable without further modification, the reply must distinctly and specifically point out the supposed errors in the examiner’s action and must respond to every ground of objection and rejection in the prior Office Action in the same vain as given above, 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

The examiner also points out, due to the change in practice as affecting final rejections, older decisions on questions of prematurity of final rejection or admission of subsequent


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amendments do not necessarily reflect present practice. "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)" (emphasis mine), see MPEP 706.07(a).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fidei whose telephone number is (571) 272-4553. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The Official Fax number to file responses to this Office Action is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David T. Fidei
Primary Examiner
Art Unit 3728

dtf
April 6, 2006